



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/933,818 | 08/22/2001 | Jean-Michel Bernardon | 016800-451 | 7237 |

7590 04/19/2005

Norman H. Stepno, Esquire
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

JIANG, SHAOJIA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,818

Applicant(s)

BERNARDON ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,8-17 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,8-17 and 22-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

HL

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on January 3, 2005 wherein the instant specification has been amended as to page 1 "In the Cross-Reference" [0002]; claims 2-3, 8-17, and 22-31 have been amended. Claims 1, 4-7, and 18-21 are cancelled previously.

Currently, claims 2-3, 8-17, and 22-31 are pending in this application.

Claims 2-3, 8-17, and 22-31 are examined on the merits herein.

Applicant's amendment which amends the specification filed January 3, 2005 with respect to the objection to the specification of record in the Office Action dated July 1, 2004 has been fully considered and found persuasive. Therefore, the objections is withdrawn.

Applicant's amendment which amends claims 2-3, 8-17, and 22-31, filed January 3, 2005 with respect to the rejection made under 35 U.S.C. 112 first paragraph for lack of scope of enablement of record stated in the Office Action dated July 1, 2004 has been fully considered and is found persuasive to remove the rejection since the particular skin disorders such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters have recited. Therefore, the said rejection is withdrawn.

Art Unit: 1617

Applicant's amendment which amends claims 2-3, 8-17, and 22-31, filed January 3, 2005 with respect to the rejection made under 35 U.S.C. 112 second paragraph for as being indefinite of record stated in the Office Action dated July 1, 2004 has been fully considered and is found persuasive to remove the rejection since the particular skin disorders such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters have recited. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 31 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular agents such as one retinoid, vitamin D, corticosteroid disclosed in the specification (see page 8) in co-administering the particular compound of formula (I) herein employed in methods for treatments herein, does not reasonably provide enablement for the employment any substances represented by “agent for combating free radicals”, or “ion channel blocker” in combination with the particular compound of formula herein to be administered for the claimed methods of the particular treatments herein, i.e.,

Art Unit: 1617

particular barrier function such as an epidermal lipid secretion disorders in a patient, for same reasons of record stated in the Office Action dated July 1, 2004.

These recitations, "agent for combating free radicals" and "ion channel blocker", are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to methods of treating a barrier function, and an epidermal lipid secretion disorders.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claim 23 is deemed very broad since the claim reads on any agents for combating free radicals or any ion channel blockers employed in the claimed methods of treatment herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants in claim 23, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997). The CAFC clearly states that “[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus..” at 1406 (emphases added).

In the instant case, “agent for combating free radicals” and “ion channel blocker” recited in the instant claim are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. Moreover, the specification does not provide those particular compounds for each kind of functional compounds for the claimed method of treatment herein.

Thus, Applicants functional language at the points of novelty in the claim fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph, since it fails to provide those elements required to practice the inventions, nor “inform the public during the life of the patent of the limited of monopoly asserted” (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

Art Unit: 1617

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, except those particular compounds of formula disclosed in the specification, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the claimed method of treatment herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects for treatment of particular skin diseases such as roascea, a skin pigmentation disorder, a seborrhoeic function disorder, a barrier function, and an epidermal lipid secretion disorders, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a human), the *combination* of the instant compound of formula (I) and any compounds represented by “agent for combating free radicals” or “ion channel blockers”. See text book “Goodman & Gilman’s The Pharmacological Basis of Therapeutics” regarding

Art Unit: 1617

possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that “The frequency of significant beneficial or adverse drug interactions is unknown” (see the bottom of the left column of page 51) and that “Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed” and that “The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences” (see the right column of page 51) (emphases added).

In the instant case, in the absence of fully recognizing the identity of the members genus herein except those particular compounds of formula in the specification, one of skill in the art would not be able to fully predict the possible treatments herein and possible adverse effects occurring with many compounds having claimed functional properties and their combinations to be administered to a host in the claimed method herein. Thus, the teachings of the “Goodman & Gilman's” book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that the specification provides no working examples, i.e., testing results or data in vitro or in vivo, demonstrating that the instant compound of formula (I) in co-administering the particular agent for combating free radicals or particular ion channel blocker, for the instant methods of treatments.

Art Unit: 1617

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations to be administered to a host employed in the claimed methods of the particular treatments herein, with no assurance of success.

Response to Argument

Applicant's arguments filed January 3, 2005 with respect to the rejection of record in the previous Office Action have been fully considered but are not deemed persuasive. These arguments are believed to be addressed by the rejection presented above.

Additionally, Applicant asserts that the claims 17 and 31 required no undue experimentation since they are art-appreciated. Contrary to Applicant's assertion, first,

Art Unit: 1617

the specification as originally filed does not provide adequate support for the generic claimed herein “agent for combating free radicals”, or “ion channel blocker”. In this regard, there is no definition for “agent for combating free radicals” or “ion channel blocker” in the specification, nor a single particular “agent for combating free radicals” or “ion channel blocker” disclosed in the specification. Further the specification provides no working examples, i.e., testing results or data in vitro or in vivo, demonstrating that the instant compound of formula (I) in co-administering the particular agent for combating free radicals or particular ion channel blocker, for the instant methods of treatments.

Thus, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would not be able to fully predict the possible treatments herein and possible adverse effects occurring with many compounds having claimed functional properties and their combinations to be administered to a host in the claimed method herein. Therefore, the instant claimed invention is highly unpredictable.

As a result, necessitating one of skill to perform an exhaustive search and undue experimentation for the embodiments of any compounds having “agent for combating free radicals” or “ion channel blocker” recited in the instant claims suitable to practice the claimed invention, with no assurance of success.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 112, first paragraph, for lack of scope of enablement. Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3, 8-17, and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernardon (5,763,487), essentially for same reasons of record stated in the Office Action dated July 1, 2004.

Bernardon discloses that the active instant compounds of formula (I) including the particular elected compound (the chemical name disclosed at col.3 lines 50-53) are useful in methods of treating dermatological, and skin and hair conditions/disorders broadly such as dermal or epidermal proliferations, a keratinization disorder, and skin aging photoinduced or chronological. See abstract, col.1-2, col.3 lines 50-53, Example 20 at col.16 and claims 12-25. Bernardon also discloses the employment of retinoids, particular vitamin D compounds, corticosteroid, particular α -hydroxy or α -keto acids, and ion channel blockers in the combination with the instant compounds in methods therein (see col.6 lines 67, col.7 lines 52-57). Bernardon further discloses that the administered route is topical, enteral, parenteral, or ocular (see col.7 lines 9-11 and 23-33)).

Note that Bernardon discloses the effective amounts of the compound herein in the range of daily dose of about 0.01 to 100 mg/kg of body weight (see col. 7 lines 19-20 and claim 17), which are within or overlapping with the effective amounts, daily dose

Art Unit: 1617

of about 0.001 to 100 mg/kg of body weight, indicated in Applicant's specification (see page 6, [0029] of the specification).

Bernardon does not expressly disclose a method for treating particular skin disorders, such as an epidermal lipid secretion disorder and the skin disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction by administering the particular compound of Bernardon.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound of Bernardon in a method for treating particular skin disorders, an epidermal lipid secretion disorder and the skin disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular compound of Bernardon in a method for treating particular skin disorders, an epidermal lipid secretion disorder and the skin disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction, because the compound of the prior art is known to be useful in treating dermatological, and skin and hair conditions/disorders such as dermal or epidermal proliferations, a keratinization disorder, and skin aging photoinduced or chronological broadly according to Bernardon. Thus, the dermatological, and skin and hair conditions/disorders taught by Bernardon would encompass the disorders of the barrier function of human skin such as an epidermal

Art Unit: 1617

lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction.

Therefore, the patient population in Bernardon is deemed to encompass the patient herein suffering from the disorders herein.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular compound of Bernardon would have beneficial therapeutic effects and usefulness in methods for treating particular skin disorders such as an epidermal lipid secretion disorder and the skin disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction by administering the same effective amounts of the same compound of Bernardon.

Response to Argument

Applicant's arguments filed January 3, 2005 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action July 1, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that

"there is nothing in Bernardon to motivate or suggest to one of skill in the art to modify Bernardon's methods so as to treat the now-enumerated disorders of the barrier function of skin. By extension, even if one of skill in the art had been so motivated, there would be no reasonable expectation of success for such a modification, and thus no

Art Unit: 1617

prima facie case of obviousness, because the disorders addressed by Bernardon are so very different than disorders of the barrier function of skin." (see page 13-14).

The motivation has been clearly addressed in the previous Office Action, since the dermatological, and skin and hair conditions/disorders taught by Bernardon would encompass the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction.

Therefore, the patient population in Bernardon is deemed to encompass the patient herein suffering from the disorders herein.

Therefore, one of ordinary skill in the art would have reasonably expected that the particular compound of Bernardon would have beneficial therapeutic effects and usefulness in methods for treating particular skin disorders such as an epidermal lipid secretion disorder and the skin disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters resulting from mechanical friction by administering the same effective amounts of the same compound of Bernardon, with reasonable expectation of success.

Note that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135,139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). The burden is shifted to Applicant to show factually supported objective evidence to rebut the prima facie case of obviousness over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No. 5,763,487 (Bernardon) for same reasons of record stated in the Office Action dated July 1, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating dermatological disorder comprising administering the same particular compound of formula (I), in the same effect amount.

The claims of the instant application is drawn to a method of treating the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters.

As discussed above, the claimed method herein is seen to be obvious over the claims in the patent.

Thus, the instant claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No. 5,763,487.

Claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 26, 28, and 35-36 of U.S. Patent No. 6,156,750 for same reasons of record stated in the Office Action dated July 1, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating dermatological disorder, epidermal and/or dermal atrophy, a sebaceous function disorder comprising administering the same particular compound of formula (I), in the same effect amount.

The claims of the instant application is drawn to a method of treating the disorders of the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters.

Based on the same rationale as the obvious rejection under 103(a) set forth above, the claimed method herein is seen to be obvious over the claims in the patent.

Thus, the instant claims 2-3, 8-17, and 22-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 26, 28, and 35-36 of U.S. Patent No. 6,156,750.

Claims 2-3, 8-17, and 22-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-29 and 32-41 of copending Application No. 10/224,449 for same reasons of record stated in the Office Action dated July 1, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to the same method of treatment for the barrier function of human skin such as an epidermal lipid secretion disorder and is the skin barrier function disorder in premature children born before 33 weeks of age, lip fissures, chapped lips, or blisters, comprising administering the same since the structural formula (I) in claim 28 of the copending application overlaps and/or read on the instant structural formula (I) in claims 2 and 22.

Thus, the copending Application No. 10/224,449 and the instant claims are seen to substantially overlap.

Thus, the instant claims are seen to be obvious over the all claims of copending Application No. 10/224,449.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
April 12, 2005